

REPLY TO:

- 135 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510-1501
(202) 224-3744
www.grassley.senate.gov
- 721 FEDERAL BUILDING
210 WALNUT STREET
DES MOINES, IA 50309-2106
(515) 288-1145
- 111 7TH AVENUE, SE, Box 13
SUITE 6800
CEDAR RAPIDS, IA 52401-2101
(319) 363-6832

United States Senate

CHARLES E. GRASSLEY
PRESIDENT PRO TEMPORE EMERITUS
WASHINGTON, DC 20510-1501

REPLY TO:

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320 6TH STREET
SIOUX CITY, IA 51101-1244
(712) 233-1860
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(712) 322-7103

May 10, 2022

The Honorable Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Califf,

I am writing with concern about the current shortage of infant formula in Iowa, and nationwide. Access to a steadfast, nutritional food supply is critical for all Americans, especially children. As supply chain shortages continue to impact families, I ask that the FDA prioritize our nation's critical need for infant formula and do what the agency can to ease the shortages.

As you likely know, supplies of infant formula have significantly decreased over the last few months. At the end of April, out-of-stock formula percentage increased to 40%, leading many retail stores to limit consumer purchases of formula. Further, in six states including Iowa, more than half of all baby formula was completely sold out during the week of April 24th. While the most common use of formula is feeding infants, many children and adults who are fed through feeding tubes also rely on formula for all of their nutrition. This is a staple that cannot be substituted.

With inflation at a 40 year high, Americans are already experiencing strain and adversity when they make trips to their local grocery stores. Many families in Iowa and across the U.S. rely on formula, but current supply chain issues and high prices are forcing low and middle income Americans to stretch their dollars and their formula even further. Shortages are also causing families to turn to unsafe methods of feeding their babies, such as making homemade formula or adding extra water to a bottle to stretch their supply. These makeshift methods of making up for a lack of supply in stores can be deadly.

I recognize the impact the COVID-19 pandemic and decreased workforce capacity has had on our supply chains. However, it is imperative that Americans have access to food that infants and others need to survive. It is the utmost importance to our families across the country that a

RANKING MEMBER,
JUDICIARY

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reliable supply of formula is reestablished immediately.

Therefore, I ask that you respond to the below questions by May 24, 2022. Please number your responses.

1. While there have been ongoing shortages for more than six months, the recent recall of Similac formulas produced by Abbott Laboratories and subsequent shutdown of the facility in Sturgis, Michigan have exacerbated the shortages. What steps has the FDA taken to allow the company to quickly resume the safe production of formula at this facility?

2. What are the plans to mitigate the effects of the recent recall of formula on the supply of formula across all brands?

3. What actions is the FDA taking to alleviate shortages and when does the FDA estimate that Americans will once again have reliable access to formula?

4. Does FDA have any plans to modify oversight or investigation procedures to ensure that in the future, families have consistent access to safe formula?

Should you have any questions please reach out to my office. On behalf of all Iowa families, I ask for a detailed, prompt, and thorough response.

Sincerely,

A handwritten signature in black ink that reads "Chuck Grassley". The signature is written in a cursive, slightly slanted style.

Charles Grassley
United States Senator